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WHAT'S IN AN APRICOT?: THE SEEDS OF LIFE AND DEATH

Gregory P. Drescher

I. Introduction

Terminally ill patients are constantly seeking and hoping for the discovery of that miracle treatment which will put an end to their suffering and provide them with a new chance at life. For those of them with cancer, that treatment may already exist. For decades, the medical profession has known the conceivably life-saving effects of a simple extraction from apricot seeds – commonly known as Laetrile.¹ The medical community has not been in wide agreement on the effectiveness of this product, though. In addition, the product has never been approved by the FDA, thus tying the believers' hands in attempts to aid the dying in their last days with any possible cure. But for the interference of the government in its quest to provide safe and effective drugs, many of those already in the grave may have been saved if they had only known that this treatment exists. The critical issue of when it is proper for the government to intervene in people's personal choices and the potentially devastating results on their lives and bodies is instrumental in the development and approval of

¹Laetrile is the name of a product whose major component or ingredient is the chemical amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds and in other plant material. *Bjgh~rf~zdv. Ink~..Sta~s*, 438 F.Supp. 1287, 1295 n.17 (W.D. Okla. 1977). Additionally, Laetrile, Amygdalin and Vitamin B-17 are all one in the same, and the term Laetrile will be used to represent all three. *Ejgh~rbr4v. Lnii~4.Sig~*, 424 F.Supp. 105, 106 (W.D. Okla. 1977).

experimental new drugs that could aid in wiping out life-threatening illnesses from society. This paper serves as a preliminary guide to the issues at stake when government policies and standards stand in the way of experimentation and innovation.

Many complex issues arise when evaluating the ramifications of the FDA's treatment of [aetrile. While the implications of the strife created by Laetrile have much farther reaching effects regarding FDA's treatment of specialized procedures for life-threatening ailments and drugs, this paper will not explore the broader elaborate issues involving such experimental drugs or the extended history of the various products that this controversy has evolved around. Instead, this paper is limited in scope to the competing interests among the government, the doctors, the patients, and the general public, and the proper means of balancing these interests to derive the greatest benefit to all Furthermore, the relation of this controversy to the issues elicited in debates over the right to die and the foundational basis of death with dignity will be examined.

This paper's subsequent evaluation of the competing interests surrounding the administration of Laetrile leads me to the conclusion that several goals must be kept in mind when developing appropriate solutions. As will be displayed, paternalistic governmental intervention must be eliminated to prevent the continuance of a policy that causes desperate people – particularly the affluent who can afford it – to go to alternative sources, including foreign countries and the black market, for treatment that may serve to prolong their

lives. To supplement this, doctors must be allowed to go about their jobs, free from the fear of not being able to treat their patients adequately due to the unavailability of Laetrile or even potential criminal prosecution. In addition, the right of privacy must be recognized and enforced in this situation to free up patient autonomy and freedom of choice by making the product accessible through informed consent and exploration of all possible treatments. This will in turn provide public awareness of new avenues of health care and allow willing patients to serve as test subjects for future treatment. Finally, the overwhelming interest of the right of a person to live and die with dignity must be recognized and respected.

H. History in the Courts and Government Involvement: The Rethinking of Decisions

For several decades, Laetrile has been used by many doctors as a last resort treatment of patients who have no other hope of survival. While the effectiveness of this strange product, derived from apricot seeds, is unproven and pronounced by many to be mere quackery, a large group of doctors believe that it can have a beneficial effect.² In fact, a report of the Cancer Commission of the California Medical Association in 1953 acknowledges the long-standing use of Laetrile. Although the report concludes that it is ineffective as a complete cure for cancer, it does state that the drug is generally recognized as safe and perhaps even palliative to some degree.³

Although doctors have been clandestinely treating their patients

²See *Biatkivird v. In & Sia*, 438 F.Supp. 1287, 1294 n. 15 (W.D. Okla. 1977).

³*B. uihrf t dv. IJnk .S1a*, 429 F.Supp. 506, 512 (W.D. Okla. 1977).

with Laetrile for decades, the issue was not thrust into the limelight until after the 1962 Drug Amendments and the refocusing of FDA enforcement.⁴ After the withdrawal of Krebiozen from the market as a result of its classification as an illegal new drug, cancer patients spoke out more vigorously. The FDA attempted to do the same with Laetrile by banning interstate shipment of it since an NDA had not been filed or approved on the drug's behalf⁵ The issue did not fully reach the public spectrum and political context, though, until the case of *Jewett v. FDA*.⁶

For the first time in the history of the FDA, an injunction was issued against the agency, precluding it from preventing the importation and administration of a drug as a treatment for disease. The Oklahoma District Court found that laetrile is not a toxic or harmful substance if used in proper dosage but is on the other hand an alternative treatment of cancer which can be used in lieu of surgery or radiation cobalt.⁷ The court found that the FDA's inaction in approving Laetrile as a treatment for cancer resulted in the deprivation of terminal patients' free choice in opting for such treatment. Therefore, the court ruled, that irreparable harm to the plaintiff overshadows the possible harm to the defendants or other interested persons⁸ and issued the aforementioned injunction. An appeal followed which resulted in the injunction being

⁴For a thorough discussion of the efforts of cancer victims to secure the use of Laetrile for treatment and the subsequent extensive history in the courts, see Peter Barton Hutt & Richard A. Merrill, *Use of Laetrile for Cancer*, in Food and Drug Law 557-59.

⁵See *Leitch v. Calkins*, 375 F.2d 105 (7th Cir. 1967); *Buth v. Anderson*, 379 F.2d 641 (7th Cir. 1967); *Jewett v. Burkhart*, 479 F.2d 242 (7th Cir. 1973).

⁶ 5 F.Supp. 1208 (W.D. Okla. 1975).

⁷ *Id.* at 1214-15.

⁸ *Id.* at 1214.

upheld⁹ and the case being remanded to the FDA to provide an administrative record containing substantial evidence of Laetrile's status as a new drug.¹⁰ The case went on to become certified as a class action suit and the district court reaffirmed the injunction, now pertaining to all terminally ill cancer patients who had no other possible form of treatment, who would receive the drug in conjunction with other treatments, or who desired Laetrile after being fully informed of all possible modes of treatment.¹¹ After much debate, the FDA established in 1977 that it still had authority over the drug since it was illegal and distributed in interstate commerce.¹² The district court once again affirmed the error in the FDA's judgment and reinstated the injunction, invoking constitutional grounds of the right of privacy.¹³ The Tenth Circuit then reviewed the decision and upheld the injunction for terminally ill patients in need of intravenous injections of Laetrile by a physician.¹⁴ The long debate over this novel form of judicial

⁹ *United States v. Laetrile*, 542 F.2d 1137 (10th Cir. 1976).

¹⁰ *United States v. Laetrile*, 424 F.Supp. 105 (W.D. Okla. 1977).

¹¹ The injunctive order of the court included the requirement that an affidavit be signed by a physician when providing Laetrile as treatment:
Such affidavit shall include the following:

1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and
2. (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or

(b) that laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or

(c) that the patient has made a knowing and intelligent election to take laetrile after being fully apprised of the full range of recognized treatments available and of the fact that laetrile is considered by most cancer experts to be of no value in combatting the disease.

Rutherford v. Rutherford, 429 F.Supp. 506, 513 (W.D. Okla. 1977). The injunction covered all agents of the government and enjoined [them] from impeding or preventing the importation and interstate transportation of laetrile by any members of the plaintiff class or their duly designated agents. *Id.*

¹² Commissioner of Food and Drugs announced, Laetrile is not generally recognized by qualified experts as a safe and effective cancer drug and "it is not exempt from the pre-market approval requirement for new drugs by virtue of the 'grandfather' provisions of the Act. *United States v. Laetrile*, 438 F.Supp. 1287, 1289 (W.D. Okla. 1977), citing 42 Fed.Reg. 39768-39806 (1977).

¹³ *Id.*

¹⁴ *United States v. Laetrile*, 582 F.2d 1234 (10th Cir. 1978).

intervention versus agency discretion was destined to appear before the United States Supreme Court.

The Supreme Court, in a surprising move that would reverberate throughout the lower courts, ruled that the FD&C Act makes no special provision for drugs used to treat terminally ill patients.¹⁵ In so ruling, the Court recognized the inherent danger for terminal patients in doctors promoting the use of unproven drugs in lieu of conventional treatments. As the Court stated, [f]or the terminally ill ... a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit,¹⁶ especially when the choice to change treatments would no longer exist afterward. As a result of this ruling, the case was remanded to determine the validity of the constitutional arguments and the status of the injunction.

Pediatric for the first time, the Tenth Circuit arrived at the heart of the matter and viewed the issue as a constitutional conflict between the patient's right to privacy in determining the appropriate individual treatment and the governmental interest in protecting public health.¹⁷ The court limited the right of the patient by coming down on the side of the government and finding the need for regulation of Laetrile as a drug. The case was remanded to the district court to resolve the issue of the injunctions, which were subsequently dissolved and the complaint dismissed.¹⁸ Although further futile litigation occurred at

¹⁵ *Junitz v. Slaters*, 442 U.S. 544, 551 (1979).

¹⁶ *Id.* at 556.

¹⁷ *Uhl v. Junitz-Slaters*, 616 F.2d 455 (10th Cir. 1980). See also *JJDJJAv*. *Unii d Slaters*, 616 F.2d 1120 (9th Cir. 1980).

¹⁸ 1983- 1984 Jud. Rec. 173 (W.D. Okla. 1984).

the behest of the plaintiffs,¹⁹ the matter was essentially resolved in favor of the government.

The issue framed by the Tenth Circuit — although deficiently explored — is the foundation for future evaluation of the use of Laetrile. The court rightfully saw this as a conflict between patient autonomy and the government's broad responsibility to the general public's health and safety. Absent from the court's analysis, though, are the various other interests at stake, involving not only the government and the patient, but the doctors and the general public as well.

m. Governmental Interests

The government serves a vital role in our society by protecting the health and safety of the general public. For this purpose, the government has enacted much legislation and set up a multitude of agencies that regulate crucial areas of citizens' lives. As with any regulation, certain rights are encroached upon and a proper balance must be derived to establish policies that will enable citizens to live freely, but safely.

The Food and Drug Administration is perhaps the most notable agency involved in assessing public health and safety. The regulations passed by the FDA are aimed to guarantee the safety and integrity of food, drugs, cosmetics, and medical devices. For the purposes of analysis, the FDA's standards in approving drugs must be briefly examined.

Due to the potential for both great physical benefit and physical harm, the FDA has imposed stringent standards when evaluating drugs. New

¹⁹See Peter Barton Hutt & Richard A. Merrill, *Use of Laetrile for Cancer*, in *Fm 4a* (1981) 559.

drugs, in particular, are subject to the most exacting premarketing stages before being approved for nationwide sale, ranging from preclinical research to clinical research (IND, Phases I, II, III) to FDA evaluation of a new drug application.²⁰ The ostensible goal of this elaborate process is to establish the safety and effectiveness of each drug product. While this laudable purpose is vital in assuring the general public of the integrity of pharmaceuticals, those who are terminally ill are justifiably frustrated by such a time-consuming process.

For cancer patients with a limited time frame for treatment, the goals of the FDA are conceivably insignificant. If a product does not get out on the market in time, the patient will have no opportunity to enjoy the pleasures of knowing that the drugs she would have been using are safe and effective. As the Tenth Circuit eloquently stated:

[W]hat can generally recognized as safe and effective mean as to such persons who are so fatally stricken with a disease for which there is no known cure? What meaning can effective have in the absence of anything which may be used as a standard? ... What can effective mean if the person, by all prevailing standards, and under the position the Commission takes, is going to die of cancer regardless of what may be done.... Clearly the terms have no meaning under these circumstances... •²¹

Recognizing the significance of getting drugs to terminally ill patients, the FDA has made certain provisions regarding an expedited approval

²⁰For a complete description of the rigorous procedures followed in approving drugs, see Peter Barton Hutt & Richard A. Merrill, *Human Drugs*, in Food and Drug Law 378-63 5.

²¹*Rudin v. L. d. S. I. A.*, 582 F.2d 1234, 1237 (10th Cir. 1978).

process and treatment IND's for those patients who can pay for them. Neither of these scenarios had any effect on the status of Laetrile, though; as described *supra* in section II, the FDA refused to take action on the status of Laetrile since no NDA existed at the time. At the same time, the FDA was forbidding the importation of Laetrile through its interstate commerce enforcement procedures.²² Thus, this effectively denied generations of cancer patients even the hope that the drug would soon be readily available.

To only view this situation from the cancer patients' perspective, though, would be unfair to the FDA. While the lives of these patients are of paramount concern, the wider effects of condoning the usage of an unapproved drug *must* be examined. The FDA's basic credibility is at stake. If a drug for cancer patients was rushed through approval which later was found to be toxic and shortened patients' lifespans, the FDA would face a debacle. As things now stand, the confidence of the general public in the drug approval process is somewhat weakened by the tremendous delays and years of red tape. At the same time, the public must understand the limited resources of the FDA, in addition to the overwhelming concern of another drug scandal. Future generations of cancer patients will also benefit from extensive pre-testing to determine if the use of Laetrile is truly efficacious as a substitute for already proven modes of treatment. Therefore, although the FDA's inaction may be viewed as unsympathetic by some, the FDA does have an important interest in exercising caution

²² See *S&H Green Stamps v. International Alliances of Theatrical Stage Employees & Moving Picture Operators of U.S. and Canada*, 70 F.Supp. 1008 (D.C.Cal. 1947), *aff'd* 165 F.2d 216 (9th Cir.), *cert. denied*, 334 U.S. 812.

in approving any new drug product.

The government as a whole also has many interests in regulating the use of Laetrile as against any individual interests in receiving the personally desired medical treatment. As expressed by the

Massachusetts Supreme Judicial Court, the State has an important interest in the preservation of life; the protection of the interests of innocent third parties; the prevention of suicide; and maintaining the ethical integrity of the medical profession.²³ Evaluated together, the predominant state interest must be in the area of the preservation of life.²⁴ The problematic feature of this interest is in the potential for divergent interpretations. Those in favor of government interventionism into personal lives tend to use this phrase broadly to encompass personal decisions in every aspect of life. The interpretation which is more reasonable is one that focuses on the government's duty to protect its citizens from intrusive and unwanted bodily attacks. The government has no true interest in pronouncing what people are to do with their own lives when their actions will have no substantial effect on other people's lives. In the case of terminally ill cancer patients, this is even more obvious. If a person is going to die within a short time, the government has no interest in forcing that person to undergo every conceivable treatment that is approved, while denying him

²³Superintendent of Beichertown State School v. Siik-wi-z, 373 Mass. 728 (1977) (setting procedures for guardian refusing conventional treatment for incompetent patient suffering from leukemia). See also John F. Kennedy Memorial Hosp. v. - 58 N.J. 576 (1971); Unit-d..Stai- v. (j-rg-, 239 F. Supp. 752 (D. Conn. 1965); Long Island Jewish-Hillside Medical Center v. 73 Misc. 2d 395 (N.Y. Sup.Ct. 1973); ki W-b-diaL, 79 Misc. 2d 753 (N.Y. Sup.Ct. 1974); LuI- Ka[waU1, 199 N.W.2d 147 (Iowa 1972).

²⁴As asserted by the Supreme Court, the State may simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual -mzanv. Director. Missouri Dept. of Healthy 110 S. Ct. 2841, 2853 (1990).

the option of using a drug he believes will help him more.²⁵ The government may argue that this is equivalent to the patient committing suicide by refusing conventional therapy, but that is a matter of individual choice. In fact, most courts have recognized the right of a competent patient²⁶ to refuse medical treatment, even if this action will result in death²⁷ Therefore, it is apparent that the government's interest in preserving life has been subject to limitations based upon the weight of the competing interests. To back off on this position, though, would be paramount to a government recognition of its own limitations in providing for the public's health and safety, particularly the FDA's problems discussed above.

As a result, terminal patients have been forced to seek other means of acquiring treatment with Laetrile. On the whole, the FDA has directed its attention to other pharmaceuticals, thereby not punishing the importation of Laetrile as long as no commercialization results. Consequently, a large black market has developed which provides the drug at extremely high cost to a limited number of people who know how to seek it and can afford it. Many others travel to Mexico and even Germany, where the drug is more readily available; unfortunately, this causes patients to abandon treatment with their own doctors, sometimes leaving behind an intense trusting relationship. Seeing the

²⁵To speak of laetrile as being unsafe for these people is bizarre. Additionally, it is connotative of a paternalism incompatible with this nation's philosophy as to the proper relationship between the government and the citizenry. *Buthrik v. Ind...*, 429 F.Supp. 506, 509 (W.D. Okla. 1977).

²⁶This paper does not deal with the increasingly complex issues arising from substituted judgment or incompetency.

²⁷*See, e.g.,* *Irvin v. Massachusetts*, 197 U.S. 11 (1905); *Edwards v. Ruzicka*, 44 Misc. 2d 27 (N.Y. Sup. Ct. 1962); *In re Estate of Brooks*, 32 Ill. 2d 361 (1965); *Isquith v. Drn...*, 294 A.2d 372 (D.C. Ct. App. 1972); *Holmes v. Silbert*, 340 F.Supp. 125 (D. Ut 1972).

undesirable effects of the FDA's inaction, one-third of the states have reacted by legalizing the drug and eliminating many of the barriers that prevent people from being treated²⁸ While these efforts have been partially successful in providing the treatment to many patients, the majority of cancer victims still do not have this resource. One of the main problem areas is the inadequate acknowledgment of the doctor's prominent role in potentially providing this drug to likely candidates.

LV. The Doctor's Role and Interests

The traditional role of the doctor is to cure the ill and comfort and ease the dying. This duty to treat encompasses all treatments that are generally recognized by the medical profession to be safe and effective. While doctors are subject to restrictions by the FDA, the predominant concern of physicians is to provide the best quality care and healing to all their patients.

The unapproved status of the drug Laetrile increases the difficulty of an already burdensome job. Since no validated test exists as to the efficacy of such treatment for cancer patients, doctors are uncertain about whether this is truly an option. Many doctors feel, though, that it cannot hurt to at least try Laetrile as a last-ditch effort to combat cancer before death. Unfortunately, the current status of the drug makes its distribution unthinkable in most instances. The limited availability makes the cost prohibitive and only allows the affluent to even consider it as an option. In addition, since Medicare and Medicaid do not pay for experimental drug treatments, both the indigent and the elderly

²⁸New York was one such state to address the concerns involving the distribution of this drug:

are inequitably affected. Thus, the doctor's role to strongly advocate for her patients is frustrated by inadequate availability of Laetrile in a majority of the states, along with excessive restrictions as to its usage.

In addition to the exorbitant cost of treatment, doctors remain reluctant to prescribe Laetrile due to fear of both criminal prosecution and malpractice liability. As the Tenth Circuit succinctly stated, the plaintiff in order to have and use B17 or laetrile is subjecting himself and his agent to criminal prosecution should plaintiff contravene prohibitions set out in 355 by making what plaintiff feels is a life versus law decision.²⁹ This decision is admittedly more difficult for the patient since her life is the one at stake, but the possibility of criminal prosecutions is even more dangerous when applied to doctors. While the patient realistically has nothing to lose through being charged criminally (she will die without the drug), the doctor has a disincentive to even discuss the possibility of attempting treatment. Not mentioning Laetrile would not subject the doctor to any malpractice liability because it is not a generally recognized form of treatment. Ironically, it is once the doctor refers to the possibility of such treatment out of genuine concern for the patient that liability can activate. This contravenes the state interest in preserving the integrity of the medical profession.³⁰

Only by guaranteeing that doctors will remain free from criminal prosecutions and unreasonable malpractice liability, as long as the patient gives

²⁹Continental Oil Co. v. F n i i L _ 1 ., 338 F.2d 780(10th Cir. 1964).

³⁰There is a state interest in the protection of the medical profession's desire to act affirmatively to save life without fear of civil liability. Superintendent of Belchertown State School v. F a j j ~ y j ~, 373 Mass. 728, 741 (1977). See also Application of the President & Directors of

informed consent and is apprised of all possible modes of treatment, will doctors be able to fulfill their roles as healers and comforters, not hiders of the truth.

If the shackles of liability are lifted from the doctor's hands, the beneficial results will foster awareness and potential innovation. Doctors will be more open about the effects of treatment with Laetrile, thereby creating a self-made case study of its effectiveness. In fact, doctors should be required to report the use and effectiveness to the National Cancer Institute so that a national record can be compiled. Danger does exist as to the potential deleterious side effects, the most obvious being the fact that if the drug does not work, the patient will die and will not be able to try other options. At the same time, though, doctors will be able to monitor the drug's effects openly and more easily, thus providing a possible opportunity to switch to alternative treatments if Laetrile is not having any effect.

Other problems become apparent in light of the new age of managed care, especially when issues of who will pay for the drug are examined. If patients are forced to pay out-of-pocket for Laetrile, the problem of discrimination against the poor exists. Doctors may be unwilling and unable to prescribe or even mention the drug to the indigent since they cannot afford it on their own. In addition, the wealthy cancer patients may bribe doctors to give them the medication even where it is currently illegal to do so. At the same time, physicians have a perverse incentive to not wait for the wealthy to offer, but to actually solicit large pay-offs for providing this miracle cure. In fact,

Georgetown College, Inc. 331 F.2d 1000 (D.C. Cir.), cert. denied,

377 U.S. 978 (1964). doctors motivated by greed may be fraudulently pessimistic about alternative treatments to persuade the rich to opt for the Laetrile as an expensive supplement to conventional forms of therapy.

While both forcing doctors to inform all patients as to the potential use of Laetrile and shifting the cost to the insurance carriers would eliminate some of these problems, the difficulties of administration still exist. The poor, whose contributions to the HMO are derived from Medicaid, will burden the industry by demanding the treatment in addition to conventional means of therapy. This is not necessarily a bad result if Laetrile proves to be effective, but the benefits of the drug are still disputed and unproven. In addition, doctors in managed care might have the incentive to cut costs of indigent, non-contributing patients by providing only the cheaper treatment of Laetrile – assuming the price of Laetrile declines when no longer on the black market – and allocating more money for higher levels of treatment to those who contribute more to the HMO. The poor, in effect, would be turned into guinea pigs by receiving only an unproven means of treatment. Stricter enforcement of malpractice standards would be necessary to offset this possibility, especially considering the diminished likelihood that a dying indigent patient would file a malpractice claim.

The possibility of discriminatory and inequitable distribution of Laetrile is attenuated by the restrictions placed on health care by predetermined set funds and limited choice in managed care organization& First, some doctors who do not believe in the effectiveness of Laetrile may not even tell their patients

of the treatment. Alternatively, some doctors might prefer to avoid the higher costs of proven treatments and prescribe only Laetrile, thereby freeing up funds for other patients in the HMO. With patients not being able to shop around for doctors, either option is undesirable. Perhaps a solution would be to *require* doctors to inform their patients of the possible treatment, while advising them as to the unknown nature of its effectiveness. This would eliminate the problem of different levels of informed consent and foster patient autonomy.³¹ Thus, the doctor will have performed his duty, and personal life and death decisions will fall in their proper place – the informed and unrestrained hands of the individual.

V. The General Public Interest

Not only do individual patients' rights outweigh government interests, but the interests of the general public do as well. No member of the general public can accurately know what ailments will befall him in later years; therefore, the public has a personal investment in guaranteeing that new drugs are available when their use is required. Whereas the FDA has prevented adequate testing on humans, willing patients should be allowed to participate in treatment tests. By having open testing on terminal humans, doctors and patients will no longer hide behind closed doors where any beneficial or detrimental effects are not reported. While this immediate availability of the drug may act as a disincentive for any pharmaceutical company to go through expensive testing

³¹Of course, this ignores the fact that most doctors exercise a tremendous amount of control over their patients' decisionmaking and will often be asked by the patient to basically make the decision for her. Patients tend to seek comfort in the physician's expert knowledge and assume that the doctor can make a better and more informed decision than they can.

of Laetrile's effectiveness or improve the product by promoting experiments, patients are already acting as guinea pigs in an uncontrolled and unreported experiment. The government must be honest with itself and the public by recognizing that Laetrile is currently being used behind closed doors, and by attempting to promote its safe use through proper dissemination of relevant information.

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Any concern about the large public cost for such experimentation is largely unwarranted. Arguably, there is the potential that any toxic side effects will actually result in higher health care costs to society for the resultant ailments. This fear is not justified, though, considering the already high cost to society and the health care industry of the pre-existing cancer condition. In fact, Laetrile is potentially a great cost savings if proven effective because apricots are in plentiful supply and will presumably cost far less than the phenomenal price tag of surgery and radiation cobalt. In addition, the potential toxicity of the drug has been found by almost all involved as negligible at best.³² Finally, the public interest extends to treating each member of society as a valuable individual, regardless of the costs and burdens this may place on others.³³ Recognition of the patient's right to privately decide her own fate is an essential part of this function.

VI. Patients' Individual Rights

³²The drug's reputation for nontoxicity, even among its opponents, is amply documented. *Burke v. Inland Empire*, 438 F.Supp. 1287, 1298 n.24 (W.D. Okla. 1977).

³³Where a person is terminally ill with cancer and unresponsive to other treatments, the public harm is considerably reduced. *Carnahan v. United States*, Civ. No. 77-0010-GT (S.D. Calif 1977).

Central to the entire analysis of conflicting interests is the individual right to privacy and its role in allowing patients to exercise free choice in treatment for life-threatening disease. As Justice Douglas pointed out in the pivotal case of *Roe v. Wade*, the constitutional right of privacy includes the freedom to care for one's health and person and the right to be let alone.³⁴ This right to privacy encompasses the right to refuse medical treatment and to choose between medical treatments.³⁵ It seems rather clear that this ability to refuse treatment is adequate in establishing a patient's right to refuse conventional means of therapy in exchange for either no treatment at all or for treatment with Laetrile. Although illegal in many states, the drug Laetrile does not have any known harmful results. While it may be argued that patients should only be allowed to use Laetrile in *conjunction* with accepted means of treatment, this flies in the face of the common understanding of the right to refuse treatment and amounts to a form of coercion. To prevent patients from making this choice is to deprive them of a right secured by the United States Supreme Court.

Considering the special nature of a terminal patient's condition, the courts have exercised extreme caution before imposing state authority over patient autonomy. Perhaps the most appropriate analogy is to the controversial right to die cases in which patients had no hope of recovery and sought to end their lives prematurely. While applying its analysis to a situation wherein the court had to evaluate the validity of a substituted judgment of withdrawing medical treatment for a patient in a persistent vegetative state, the New Jersey

³⁴410 U.S. 179, 213 (1973) (Douglas, J., concurring)..

³⁵See cases cited *supra* note 27.

Supreme Court stated, [w]e think that the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims.³⁶ Noting Quinlan's hopeless condition, the court felt that her interests must predominate. Supplementing this validation of patient autonomy in terminal cases, Justice Brennan has stated:

[T]he State has no legitimate general interest in someone's life, completely abstracted from the interest of the person living that life.... Thus, the State's general interest in life must accede to [the patient's] particularized and intense interest in self-determination in her choice of medical treatment. There is simply nothing legitimately to be gained by superseding her decision.³⁷

Once a patient is deemed terminal, there should be no restriction imposed on how she lives her remaining days, whether in the treatment she receives or in the manner that she dies. The government's interest in the preservation of life has no significance to those who have a radically curtailed lifespan.³⁸ In the case of cancer patients, the government arguably has more of an interest in patients actually struggling for hope by receiving Laetrile treatment, than in these patients giving up on all forms of therapy and thus taking an action that

³⁶In *the Matter of Karen Ann Quinlan*, 355 A.2d 647, 664 (N.J. 1976).

³⁷*Culzan v. Fink*, 110 5. Ct. 2841, 2870 (1990) (Brennan, J., dissenting).

³⁸Chief Justice Bird of the California Supreme Court, herself a cancer victim, lamented over this tragic scenario:

The denial to them of medical treatment, albeit unorthodox, albeit unapproved by a state agency, must surely take on a Kafkaesque, a nightmare, quality. No demonstrated public danger, no compelling interest of the state, warrants an Orwellian intrusion into the most private of zones of privacy. ¶1 The state has in the name of protecting the cancer victim criminalized the doctor who is willing to innovate, willing to try an unapproved drug with the consent of his patient. From the terminal patient's viewpoint a new depth of inhumanity is reached....

v. Fink, 591 P.2d 919 (Cal. 1979) (Bird, C.J., dissenting).

is theoretically equivalent to suicide.³⁹

VII Dying with Dignity

Disregarding all other interests invoked to dispute the right of a terminal cancer patient to attempt Laetrile as a form of treatment, one controlling principle must be cherished – the dignity of the human being. Death is the most personal and heartrending matter that anyone must encounter. Terminal patients look it in the face every day.⁴⁰ The government has no stake in how its people face this challenge. Doctors can only comfort and support their patients. The public, while presumably sympathetic for the ill and grateful not to be in the same situation, serves no function in the personal decisions that are made. This is an individual tragedy that can either be succumbed to with despair or stared down with dignity.⁴¹

The government, by imposing restrictions on how terminal patients can be treated, shows a fundamental lack of respect for this personal turmoil and the need for self-determination. To say that a person cannot attempt a treatment that some believe can give a second chance at life strips a person of his self-esteem and hope. This is not respect for the right to die with dignity.

³⁹Ironically, this is one situation where the right to privacy conforms with the idea of the right to life. Perhaps this is one of the few areas where the pro-life movement would agree with liberals, in that to deprive the patient from making her private choice to take Laetrile, the government is infringing on her right to live. If no other form of treatment is available, the government's restriction is effectively the imposition of a death sentence.

⁴⁰In my view, our understanding as to how life should end must be infused with the fundamental human moral values that serve us while we live. As we have faced life, so should we be able to face death. In the matter of Claire Conroy, 98 N.J. 321, 399 (1985) (Handler, J., dissenting).

⁴¹Dying is personal. And it is profound. For many, the thought of an ignoble end, steeped in decay, is abhorrent. A quiet, proud death, bodily integrity intact, is a matter of extreme consequence. (**nizn** v. Director.. Missouri Dept. of Health 110 5. Ct. 2841, 2868 (1990) (Brennan, J., dissenting)).

More importantly, this is a deprivation of a potential miracle, thus constricting the terminally ill from the right to *live* with dignity. In the words of Justice Stevens:

We may ... justly assume that death is not life's simple opposite, or its necessary terminus, but rather its completion. Our ethical tradition has long regarded an appreciation of mortality as essential to understanding life's significance. Lives do not exist in abstraction from persons, and to pretend otherwise is not to honor but to desecrate the State's responsibility for protecting life.⁴²

The courage to face the unknown, but inevitable, is a remarkable trait – one that should be respected, not deprived.

VIII. Conclusion

While the differences between the conflicting interests in the dispute over Laetrile seem insurmountable at first glance, a careful analysis has revealed some areas where compromise is possible to derive an acceptable result. Of first priority is the need for the courts to re-enact the *Uhl* injunction, basing such a decision on constitutional grounds involving the outweighing of governmental interests by individual privacy rights. This will reduce the FDA's concerns regarding an unspoken validation of the drug's effectiveness. As a corollary, Laetrile must be legalized in all fifty states with a statute similar to the one in New York, thereby reducing its cost by eliminating the need for a black market or foreign importation. This will make it readily available as a special category drug, prescribed by licensed physicians — and available

⁴² *Id.* at 2882 (Stevens, J., dissenting).

through pharmacists and hospitals —to terminally ill patients who exercise informed consent. In addition, criminal prosecutions and malpractice cases must be barred as long as patients are told of all their options and sign a waiver of liability. Insurance companies should also change their policies to pay for the drug as a treatment for cancer, thus eliminating any discriminatory impact upon the poor. Finally, doctors should be required to tell all appropriate patients of this option and keep a record of the results of such treatment to be compiled nationally to determine the effectiveness of Laetrile once and for all.

These solutions will ultimately stand as an acknowledgment of the utmost respect for the individual's need to live and die with dignity. As Judge Handler once said, [when cherished values of human dignity and personal privacy, which belong to every person living or dying, are sufficiently transgressed by what is being done to the individual, we should be ready to say: enough.⁴³ Cancer patients have reached that point. To the government, to the FDA, to the courts — they say enough.

⁴³In the matter of Claire Conroy, 98 N.J. 321, 399 (1985) (Handler, J., dissenting).